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ST LOUIS, MO 63102

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/005,510
Filing Date: November 08, 2001
Appellant(s): SCHASTEEN ET AL.

SCHASTEEN ET AL.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 2, 2007 appealing from the Office action mailed June 13, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Conkle et al *(WO 00/50072, published August 31, 2000).*

Brown et al *(U.S. Patent No. 6, 019, 985, published February 1, 2000).*

Evans et al *(WO 96/40234, published December 19, 1996).*

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

I. Claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148, 149-150 and 153-154 are rejected under 35 U.S.C. 102(a) as anticipated by Conkle et al *(WO 00/50072, published August 31, 2000).*

Claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148, 149-150 and 153-154 are drawn to a composition for the prevention or control of coccidiosis comprising viable sporulated oocysts of at least one species of protozoa known to cause coccidiosis wherein said composition is sterile and contains at least about 10,000 oocysts per milliliter and less than about 0.8% by weight of alkali metal dichromate as well as kits comprising the composition and instructions.

Conkle et al teach compositions comprising coccidial oocysts from *Eimeria maxima*, *E. acevulina* and *E. tenella* (page 3). Conkle et al teach that the oocyst concentration is about 10^4 to about 10^6 oocysts/ ml (page 3). Conkle et al teach that in a preferred embodiment of the invention the oxidant is hydrogen peroxide (page 8). Claim limitations such as "the composition ameliorates a decline or decrease in post-challenge performance" and "a ratio is defined by the minimum immunizing dose and

amount determined by storage high-life determinations" are being viewed as inherent and as a limitation of intended use which Conkle et al anticipate because Conkle et al teach the same composition.

With respect to the "instruction" limitation in claim 113, Conkle et al anticipate this claim limitation because the "instruction" limitation carries no patentable weight. The package insert (instructions) does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between package insert and the product, composition of matter or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. If there is no novelty in a composition itself, then a patent cannot be properly granted on the composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statues make no provision for patenting of an article or composition which is not, in and of itself, new. Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles.

The polypeptides of the claimed articles remain fully functional absent the labeling or printed instructions for use. It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in composition constitute an "intended use" for that composition. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the claims are drawn to a composition which comprises oocysts and instructions for administration of the said composition to an animal. The intended use which is recited on the package insert lacks a function relationship to the composition because the insert does not physically or chemically affect the chemical nature of the composition and furthermore, the composition can still be used by the skilled artisan for other purposes. Therefore, instructions for administering the composition is unpatentable over the prior art because the composition functions equally effectively with or without the package insert, and accordingly *no functional relationship exists between the instructions for use and the*

composition. Thus, the instructions on the package insert bears no patentable weight with regard to double patenting, 102, and 103 rejections.

The claim limitation "said composition being substantially free of bacterial contaminants which are present in said source but have been separated from oocysts by tangential flow filtration of an aqueous process medium" is a process limitation. It should be remembered that the products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Conkle et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

II. Claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148, 149-150 and 153-154 are rejected under 35 U.S.C. 103(a) as unpatentable over Conkle et al *(WO 00/50072, published August 31, 2000)* in view of Brown et al *(U.S. Patent No. 6, 019, 985, published February 1, 2000)*.

Claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148, 149-150 and 153-154 are drawn to a composition for the prevention or control of coccidiosis comprising viable sporulated oocysts of at least one species of protozoa known to cause coccidiosis wherein said composition is sterile and contains at least about 10,000 oocysts per milliliter and less than about 0.8% by weight of alkali metal dichromate as well as kits comprising the composition and instructions.

Conkle et al teach compositions comprising coccidial oocysts from *Eimeria maxima*, *E. acevulina* and *E. tenella* (page 3). Conkle et al teach that the oocyst concentration is about 10^4 to about 10^6 oocysts/ ml (page 3). Conkle et al teach that in a preferred embodiment of the invention the oxidant is hydrogen peroxide (page 8).

Conkle et al do not teach the use of *Propionibacterium acnes*.

Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases (column 3, lines 20-26 and column 4, lines 15-21). Brown et al teach that the amount of *Propionibacterium acnes* in the composition is about 0.5 mg to about 10 mg dried weight per milliliter of diluent (column 4, lines 15-21). Brown et al teach that other materials such as antibiotic, for example gentamicin, may be added to the composition comprising *Propionibacterium acnes* (column 4, lines 7-14).

Claim limitations such as, "a kit", "the composition ameliorates a decline in post-challenge performance" and "a ratio defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as limitations of intended use. The claim limitation "wherein said composition contains at least about 30 milligrams (dry weight) of *P. acnes* per milliliter" is being viewed as a limitation of optimizing experimental parameters since Brown et al teach that other initial concentrations of P acnes suspension are within the scope of the invention because the actual administration to the chick is adjusted and diluted for optimum dosages (column 4, lines 19-22).

The claim limitation "said composition being substantially free of bacterial contaminants which are present in said source but have been separated from oocysts by tangential flow filtration of an aqueous process medium" . It should be remembered that the products of the prior art reference appear to be the same or an obvious or

analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

It would be *prima facie* obvious at the time the invention was made to add the composition comprising *Propionibacterium acnes* as taught by Brown et al to the compositions comprising oocysts from the genus *Eimeria* of Conkle et al because Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases. It would be expected barring evidence to the contrary that a composition comprising

sporulated oocysts, a diluent, a buffer and a bactericide would be effective in preventing coccidiosis in animals.

III. Claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148, 149-150 and 153-154 are rejected under 35 U.S.C. 102(b) as anticipated by Evans et al *(WO 96/40234, published December 19, 1996).*

Claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148, 149-150 and 153-154 are drawn to a composition for the prevention or control of coccidiosis comprising viable sporulated oocysts of at least one species of protozoa known to cause coccidiosis wherein said composition is sterile and contains at least about 10,000 oocysts per milliliter and less than about 0.8% by weight of alkali metal dichromate as well as kits comprising the composition and instructions.

Evans et al teach compositions comprising sporulated oocysts derived form an oocysts an oocysts source comprising bacterial contamination (pages 5-6). Evans et al teach that a typical dose of sporulated oocysts is 200,000 oocysts/bird (page 5). Evans et al teach that oocysts of the invention can be treated with sodium hypochlorite and then sporulated (page 5). Evans et al teach that potassium dichromate is removed from the suspension by repeated washing of the oocysts (page 6), therefore the claim limitation , "...less than about 0.4% by weight of alkali metal dichromate" is taught by the prior art. Although Evans et al teach that the oocysts of the invention can be prepared by any of several methods known to the skilled artisan (page 5), claim limitations such as ... "said composition being substantially free of bacterial contaminants which are

present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but said bacterial contaminants can pass through the pores are being viewed as process limitations. It should be remembered that the products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

Claim limitations such as "the composition ameliorates a decline in post-challenge performance", "kit for prevention or control of coccidiosis" and "a ratio is defined by the minimum immunizing dose and amount determined by storage half-life determinations" are being viewed as a limitation of intended use.

The package insert (instructions) does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between package insert and the product, composition of matter or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. If there is no novelty in a composition itself, then a patent cannot be properly granted on the composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statues make no provision for patenting of an article or composition which is not, in and of itself, new. Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed compositions. The compositions remain fully functional absent the labeling or printed

instructions for use. It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in composition constitute an "intended use" for that composition. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, the claims are drawn to a composition comprising oocysts and instructions for administration of the said composition to an animal. The intended use which is recited on the package insert lacks a function relationship to the composition because the insert does not physically or chemically affect the chemical nature of the composition and furthermore, the composition can still be used by the skilled artisan for other purposes. Therefore, instructions for administering the composition is unpatentable over the prior art because the composition functions equally effectively with or without the package insert, and accordingly no functional relationship exists between the instructions for use and the composition. Thus, the

instructions on the package insert bears no patentable weight with regard to double patenting, 102, and 103 rejections. Evans et al anticipate the claimed invention.

IV. Claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148 -150 and claims 153-154 are rejected under 35 U.S.C. 103(a) as unpatentable over Evans et al *(WO 96/40234, published December 19, 1996)* in view of Brown et al *(U.S. Patent No. 6, 019, 985, published February 1, 2000).*

Claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148 -150 and claims 153-154 are drawn to a composition for the prevention or control of coccidiosis comprising viable sporulated oocysts of at least one species of protozoa known to cause coccidiosis wherein said composition is sterile and contains at least about 10,000 oocysts per milliliter and less than about 0.8% by weight of alkali metal dichromate as well as kits comprising the composition and instructions.

Evans et al teach compositions comprising sporulated oocysts derived form an oocysts an oocysts source comprising bacterial contamination (pages 5-6). Evans et al teach that a typical dose of sporulated oocysts is 200,000 oocysts/bird (page 5). Evan et al teach that oocysts can of the invention can be treated with sodium hypochlorite and then sporulated (page 5). Evans et al teach that potassium dichromate is removed from the suspension by repeated washing of the oocysts(page 6), therefore the claim limitation , "...less than about 0.4% by weight of alkali metal dichromate" is taught by the prior art.

Evans et al do not teach the use of *Propionibacterium acnes.*

Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases (column 3, lines 20-26 and column 4, lines 15-21). Brown et al teach that the amount of *Propionibacterium acnes* in the composition is about 0.5 mg to about 10 mg dried weight per milliliter of diluent (column 4, lines 15-21). Brown et al teach that other materials such as antibiotic, for example gentamicin may be added to the composition comprising *Propionibacterium acnes* (column 4, lines 7-14). Claim limitations such as "the composition ameliorates a decline in post-challenge performance", "kit for the prevention or control of coccidiosis comprising instructions for administration of said composition to an animal" and "a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as a limitation of intended use. Although Evans et al teach that the oocysts of the invention can be prepared by any of several methods known to the skilled artisan (page 5), claim limitations such as "... said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said bacterial contaminants using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but said bacterial contaminants can pass through the pores" are being viewed as process limitations.

It would be *prima facie* obvious at the time the invention was made to add the composition comprising *Propionibacterium acnes* as taught by Brown et al to the

coccidiosis vaccines comprising oocysts of Evans et al because Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases and Evans et al teach that vaccine compositions comprising *Eimeria* oocysts are effective at vaccinating poultry against coccidiosis (see the Abstract). It would be expected barring evidence to the contrary that a composition comprising sporulated oocysts and *Propionibacterium acnes* would be effective in preventing coccidiosis in animals.

(10) Response to Argument

I. Response to Argument Traversing the Rejection of claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148, 149-150 and 153-154 under 35 U.S.C. 102(a) as anticipated by Conkle et al.

Appellant urges that claim 1 is not only substantially free of live bacteria that can be killed by sodium dichromate but is also substantially free of dead bacteria and cellular debris that are derived from the source and remain in a vaccine composition after chemical treatment. Appellant urges that Conkle et al. describe a method for preparing a vaccine against avian coccidiosis but fail to disclose or suggest an oocyst-containing composition that is substantially free of bacterial contaminants. Appellant urges that Conkle et al. state that oocysts may be washed following sporulation to reduce the residual oxidant concentration to an acceptable level. Conkle et al. further disclose that serial washing may be conducted, preferably by membrane

filtration and most preferably by diafiltration. Conkle et al teach that serial washing steps may also reduce residual oxidant concentration in the bleached suspension. Appellant urges that it is important to understand the washing and filtration do not render a vaccine that is substantially free of bacterial contaminants. Appellant urges that Conkle et al. fail to teach or disclose a filter size small enough to prevent sporulated oocysts from entering the pores but large enough to allow bacteria to pass through the pores. Appellant urges that the filter used in tangential flow is large enough to allow bacteria to pass. Appellant urges that the composition of Conkle et al. would comprise a greater amount of bacterial debris than the composition of claim 1.

Appellant disagrees with the Examiner's position on novelty regarding the purification or production of a product by a particular process does not impart novelty or unobviousness to a product if the same product is taught in the prior art. Appellant urges that this position fails because the same product is not taught in the prior art. Appellant urges that the claim limitation "substantially free" of a specified class of bacterial contaminants, i.e. bacterial contaminants is the limitation that makes the invention differ from that of the prior art. Appellant urges that in the final Office action the Examiner failed to apply MPEP 2144.04 which states:

> Pure materials are novel vis-à-vis less pure or impure material because there is a difference between pure and impure materials. Therefore the issue is whether claims to a pure material are unobvious over the prior art.

Appellant urges that the claimed product is structurally different from the product of the prior art because of structural differences. Appellant urges that the Final Office states that well accepted meaning of purify means to clear material from unwanted

defilement or imperfection, suggesting that the compositions of Conkle et al. are purified. Appellant urges that Conkle et al. does not anticipate claim 1. Appellant urges that the Examiner is misconstruing Appellant's arguments, Appellant's do not state that Conkle et al do not remove any unwanted material. Appellant urges that Conkle et al does not teach a composition that is "substantially free" of bacterial contaminants including both viable and nonviable.

Appellant urges contrary to the Examiner's assertion, novelty requires nothing unexpected only that the claimed subject matter differs from what can be found in the four corners of a single reference. Appellant urges that unexpected properties are not a requirement for non-obviousness, but they can be relevant as secondary evidence overcoming a rejection from prima facie obviousness.

Appellant urges that a rejection under 35 U.S.C. 103(a) using Conkle et al alone has not been made. Appellant urges that in the Final Office action suggests that a side-by-side comparison be made between the claimed "vaccine" (claims are direct to composition) with Conkle et al. Appellant states "that the need for such comparison could arise only if prima facie obviousness has not been shown". Appellant urges that claim 1 is patentable over Conkle et al. Appellant urges that claims 4-8,14-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150 and 153-154 depend either directly or indirectly from claim1 and thus are patentable for the same reasons as set forth above.

Appellant urges that claims 9-10 as well as claims 11-12 which depend either directly or indirectly from 10 are thus patentable for the same reasons set forth above for claim 1. Appellant urges that claims 30 (depend from claim 29) and 142 are indirectly

dependent on claim 1 and thus are unpatentable for the same reasons as set forth above for claim 1. Appellant urges that the Examiner has misinterpreted these claims because the Examiner asserts that the claim limitation "the composition ameliorates a decline or decrease post challenge performance" are being view as inherent and intended use. Appellant urges that the composition of Conkle et al do not teach the claim limitation "the composition ameliorates a decline or decrease post challenge performance". Claim 113 depends from claim 1 and is directed to a kit. Claim 113 is patentable for the same reasons as claim 1. Appellant urges that the instructions in the kit do not merely constitute intended use but provide a functional relationship to the composition. Claim 139 recites "a ration defined by the minimum immunizing dose and amount determined by storage (half) –life determination is more than intended use.

Appellant urges that there in remote connection between the disclosure of encysted protozoa in Conkle et al and the ration and amounts recited in the claims. Appellant urges that the ration and amounts recited in claim 129 are entirely structural and is a critical and desired feature of the composition. Appellant urges that the recited ratios in the claims assure efficacy with compromising the bird's performance. Appellant urges that the Examiner has not provide evidence for her assertion and the assertion is solely hindsight reconstruction. Appellant urges that Conkle do not mention the problem of aging of sporulated oocysts during shipping and storage much less half-life determinations and ratios.

It is the Examiner's position that Appellant is arguing process limitations in a product claim. The claims are directed to a composition comprising viable sporulated oocysts. With regard to process limitations in a product claim, MPEP 2113 discloses that:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. **The patentability of a product does not depend on its method of production**. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Therefore, one of skill in the art would reasonably conclude that the patentability of the product is based on the product itself.

To address Appellant's comments regarding process limitations such as removal of bacterial contaminants, the use of tangential flow filtration and the use of filter membranes with specific pore sizes (which includes the limitations in claims 153-154), it should be remembered that the purification or production of a product by a particular process does not impart novelty to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the

product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

To address Appellant's arguments regarding MPEP 2144.04, it is noted that this does not apply to the current claims. The prior art of Conkle et al teaches the same composition comprising sporulated oocysts as the claimed invention. The claimed composition and the composition of the prior art are not structurally different. Appellant is arguing process limitations in a product claim which is address by MPEP 2113, as set forth above. Appellant is merely arguing that the claimed product is different from the product in the prior art because "tangential flow" (a process limitation) makes the claimed product structurally different because the claimed product is "substantially free from bacterial contaminant both viable and nonviable" It should be noted that claim 1 does not recite whether the bacterial contaminants that are removed from the composition of claim 1 are viable and/or nonviable contaminants. Claim 1 recites that the composition comprises "viable sporulated oocyts". Appellant is arguing limitations that are not in the claims.

The Examiner is not misconstruing Appellant's arguments regarding Conkle et al not teaching the removal of unwanted contaminants. The Examiner disagrees with

Appellant's assertion that Conkle et al do not teach a composition substantially free of bacterial contaminants. It should be noted that Appellant admits that "Conkle et al state that oocysts may be washed following sporulation to reduce the residual oxidant concentration to an acceptable level and serial washings maybe conducted preferably by membrane filtration or by diafiltration". Although the claims are directed to a product, Conkle et al teach the removal of contaminants from the suspension comprising the oocysts.

To address Applicant's arguments regarding novelty and side-by-side comparison, these considerations (side-by-side comparison) can be made in response to a rejection under 35 U.S.C. 102 regarding anticipation.

To address Appellant's comments regarding unexpected results, this consideration can be made in response to a rejection under 35 U.S.C. 103(a) regarding obviousness.

To address Appellant's argument's regarding an rejection under 35 U.S.C. 103(a) and Conkle et al., it should be noted that the Examiner agreed with Appellant that no rejection under 35 U.S.C. 103(a) has been made of record using Conkle et al. as single reference.

To address claims 4-8, 14-22, 29-20, 113-116, 118-119, 136-142, 146, 148-150 and 153-154 which directly or indirectly depend from claim 1, it is the Examiner's position that these claims are unpatentable because they are anticipated by Conkle et al. Claim 1 is directed to a composition comprising sterile viable sporulated oocysts. Conkle et al teach a composition comprising sterile viable sporulated oocysts. Claim

limitations such as substantially free of bacterial contaminants separated by tangential flow filtration is a process limitation in a product claims that does not provide a structural difference between the claimed invention and the prior art.

To address Applicant's comments regarding the composition amerliorating a decline or decrease post challenge performance is a limitation of intended use of the claimed product. Since the claimed composition and the composition of the prior art are the same and are not structurally distinct, the prior art (Conkle et al.) would necessarily be capable or performing the same as the claimed composition.

To address Appellant's comment's regarding kit instructions, it should be noted that the instructions as to how to use the kit is a limitation of intended use and has no functional relatedness to the composition. The printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition, or article of manufacture.

See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, it is stated that: Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned...In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be *new.* If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is

intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statues make no provision for patenting of an article or composition which is not, in and of itself, new.

Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The compositions remain fully functional absent the labeling or printed instructions for use.

It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03:

> Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

To address Applicant's comment's regarding, "... a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations" would be inherent in the teachings of the prior art because Conkle et al teach that encysted protozoa oocysts including *Eimeria maxima, E. mitis, E. tenella, E. acevulina, E. brumetti, E. necatrix, E. praecox* and mixtures thereof including multiple strains can be give in a single vaccine. Vaccines are known as pharmaceutical compositions that are used to immunize subjects and are thereby given in immunizing doses and can include determination by storage half-life determinations. The compositions of Conkle et al disclose that the same concentration of oocysts are used to prepare their composition as those disclosed in the claimed invention. See page 3 of Conkle et al. Therefore, this claim limitation is met by the prior art.

II. Response to Argument Traversing the Rejection of claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148, 149-150 and 153-154 under 35 U.S.C. 103(a) as unpatentable over Conkle et al in view of Brown et al.

Appellant urges that Claim 1 and Conkle et al have been discussed above. Appellant urges that Brown is directed to methods for improving immunization against coccidiosis and other bacterial, viral or parasitic diseases in poultry. Appellant urges that Brown et al fail to disclose or suggest a composition that is substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow...".Appellant urges that Brown et al is relied upon by the

Examiner for its disclosure of *P. acnes*. Appellant urges that Brown that all of the claims are patentable over Conkle et al. and over any combination of Conkle. et al and Brown et al. Appellant urges that the product-by-process limitations of in claim 1 impose structural limitations and distinguishes the claimed invention from the cited references. Appellant urges that there is no disclosure in Conkle et al. nor Brown et al. that teach a composition substantially free of bacterial contaminants removed by tangential flow filtration. Appellant urges that neither of the cited references suggest separating nonviable bacterial or other contaminants that may be present in the composition or during processing. Conkle et al. merely disclose washing steps. Brown et al do not teach or disclose removing any nonviable bacterial contaminants.

Appellant urges that the composition of claim 1 provides an advantage over other compositions (such as the composition of Conkle et al.) in that the lower amount of nonviable bacterial contaminants reduces the risk that animals administered the composition will experience a pyrogenic reaction. Applicant urges that the claimed composition has the unexpected and unique property of a lower number of nonviable contaminants that result in freedom from adverse side effects.

Appellant urges that only hindsight reconstruction afforded by Appellant's invention can it be seen that there is a need or purpose for a vaccine that is free of bacterial contaminants.

It is the Examiner's position that the combination of references teach the claimed invention.

To address Applicant's comments regarding, Conkle et al combined with Brown et al, it is the Examiner's position that the claimed compositions and the compositions as set forth in the combination of prior art teachings are not structurally different. The claims are directed to composition comprising viable sporulated oocysts (a product). The claims require that the composition comprises: 1) "sporulated oocysts", 2) wherein the oocysts are at least about 10,000 oocysts per milliliter and 3) wherein the composition is sterile and contains less than about 0.4% of alkali metal dichromate. Claim limitations such as "said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts" and "bacterial contamination using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores, but said bacterial contaminants can pass through the pores" are process limitations. The combination of prior art teachings (Conkle et al and Brown et al) teach the claimed invention because Conkle et al teach compositions comprising: 1) sporulated oocysts, 2) the oocysts are at least about 10,000 oocysts per milliliter and 3) the composition is sterile and contains less than about 0.4% of alkali metal dichromate and Brown et al teach that *Propionibacterium acnes* can be used for stimulating non-specific cell mediated immune responses in poultry at an age as early as day one or even *in ovo* and to combat coccidiosis and other poultry diseases. Thus, one of ordinary skill in the art would be motivated to

combine the teachings of Conkle et al. and Brown et al. to arrive at the claimed invention.

To address Appellant's comments regarding advantages of the claimed composition, the composition as taught by the combination of references is the same as the claimed composition. Therefore, since there are no structural differences between the two compositions, the composition as taught by the prior art would possess the same unexpected and unique properties as the claimed composition.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Therefore, combination of references teach the claimed invention.

III. Response to Argument Traversing the Rejection of claims 1, 4-22, 29-30, 113-116, 118-119, 136-142, 146, 148, 149-150 and 153-154 under 35 U.S.C. 102(b) as anticipated by Evans et al.

Appellant urges that claim 1 is not only substantially free of live bacteria that can be killed by sodium dichromate but is also substantially free of dead bacteria and

cellular debris that are derived from the source and remain in a vaccine composition after chemical treatment. Appellant urges that Evans et al. describe a method of vaccinating a domesticated bird against coccidiosis but fail to disclose or suggest an oocyst-containing composition that is substantially free of bacterial contaminants. Appellant urges that Evans et al. disclose that oocysts may be centrifuged and resuspended in deionized or distilled water. Appellant urges that Evans do not teach removing nonviable contaminants. Appellant urges that the Examiner cites page 7 of Evans et al and asserts that it describes preparation and purification of merozites and not oocysts from host cellular debris.

Appellant urges that Evans et al failed to disclose or suggest a composition substantially free of bacterial contaminants which have been separated by tangential flow filtration having a filter membrane having a pore size such that sporulated oocysts cannot enter the pores but the bacterial contaminants can pass through the pores.

Appellant disagrees with the Examiner's position on novelty regarding the purification or production of a product by a particular process does not impart novelty or unobviousness to a product if the same product is taught in the prior art. Appellant urges that this position fails because the same product is not taught in the prior art. Appellant urges that the claim limitation "substantially free" bacterial contaminants is the limitation that makes the invention differ from that of the prior art. Appellant urges that the product-by-process limitations of claim impose structural limitations and distinguishes the claimed invention from the cited references. Appellant urges that there is no disclosure in Evans et al. that teach a composition substantially free of

bacterial contaminants removed by tangential flow filtration. Appellant urges that since the Examiner has not entered a rejection under 103(a) based on Evans et al alone nor offered any prima facie case of obviousness regarding Evans et al teaching a vaccine comprising sporulated oocysts which are substantially free of bacterial contaminants there is no burden upon Applicant provide side-by-side comparison or any other secondary evidence.

Appellant urges that claims 4-8,14-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150 and 153-154 depend either directly or indirectly from claim 1 and thus are patentable for the same reasons as set forth above.

Appellant urges that claims 9-10 as well as claims 11-13 which depend either directly or indirectly from 10 are thus patentable for the same reasons set forth above for claim 1. Appellant urges that claims 30 (depend from claim 29) and 142 are indirectly dependent on claim 1 and thus are unpatentable for the same reasons as set forth above for claim 1. Appellant urges that the Examiner has misinterpreted these claims because the Examiner asserts that the claim limitation "the composition ameliorates a decline or decrease post challenge performance" are being view as inherent and intended use. Appellant urges that the composition of Evans et al do not teach the claim limitation "the composition ameliorates a decline or decrease post challenge performance". Claim 139 recites "a ratio defined by the minimum immunizing dose and amount determined by storage (half) –life determination is more than intended use.

Appellant urges that there is no remote connection between the disclosure of encysted protozoa in Evans et al and the ratio and amounts recited in the claims.

Appellant urges that the ration and amounts recited in claim 129 are entirely structural and is a critical and desired feature of the composition. Appellant urges that the recited ratios in the claims assure efficacy with compromising the bird's performance. Appellant urges that the Examiner has not provide evidence for her assertion and the assertion is solely hindsight reconstruction. Appellant urges that Evans et al do not mention the problem of aging of sporulated oocysts during shipping and storage much less half-life determinations and ratios.

It is the Examiner's position that the claimed composition and the composition of the prior art are not structurally different. The claims are directed to composition comprising viable sporulated oocysts (a product). The claims require that the composition comprises "sporulated oocysts" where the oocysts are at least about 10,000 oocysts per milliliter and less than about 0.4% of alkali metal dichromate, said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said oocysts and bacterial contamination using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores but said bacterial contaminants can pass through the pores" are process limitations. Evans et al teach compositions comprising sporulated oocysts (see page 9).It is the Examiner's position that Applicant is arguing process limitations in a product claim. MPEP 2113 discloses that:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. **The patentability of a product does not depend on its method of production.** If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Therefore, one of skill in the art would reasonably conclude that the patentability of the product is based on the product itself.

To address Applicant's comments regarding process limitations such as removal of bacterial contaminants, the use of tangential flow filtration and the used of filter membranes with specific pore sizes (which includes the limitations in claims 153-154), it should be remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in

the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

To address Appellant's comments regarding tangential flow and pore size, these limitations are process limitations. It should be remembered that the claims are drawn to product. It should be further remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. The claims are not patentable over the cited prior art.

It should be noted that the Examiner disagrees with Applicant's assertion that "the prior art does not disclose separating the oocysts from bacterial or other contaminants that may be present in the sporulation medium or in the bleached oocysts suspension". Evans et al teach the removal of contaminants from the suspension comprising the oocysts. See page 7.

To address Applicant's arguments regarding novelty and side-by-side comparison, these considerations (side-by-side comparisons) can be made in response to a rejection made under 35 U.S.C. 102 regarding anticipation.

To address Appellant's comments regarding unexpected results, this is a consideration that is made in response to a rejection made under 35 U.S.C. 103(a) regarding, obviousness.

To address Appellant's argument's regarding an rejection under 35 U.S.C. 103(a) and Conkle et al., it should be noted that the Examiner agreed with Appellant that no rejection under 35 U.S.C. 103(a) had been made of record using Evans et al. as single reference.

To address claims 4-8, 14-22, 29-30, 113-116, 118-119, 136-142, 146, 148-150 and 153-154 which directly or indirectly depend from claim 1, it is the Examiner's position that these claims are unpatentable because they are anticipated by Evans et al. Claim 1 is directed to a composition comprising sterile viable sporulated oocysts. Evans et al teach a composition comprising sterile viable sporulated oocysts. Claim limitations such as substantially free of bacterial contaminants separated by tangential flow filtration is a process limitation in a product claims that does not provide a structural difference between the claimed invention and the prior art.

To address Applicant's comments regarding the composition amerliorating a decline post challenge performance is a limitation of intended use of the claimed product. Since the claimed composition and the composition of the prior art are the same and are not structurally distinct, the prior art (Evans et al.) would necessarily be capable or performing the same as the claimed composition.

To address Applicant's comment's regarding, "... a ratio defined by the minimum immunizing dose and amount determined by storage half-life determinations" would be inherent in the teachings of the prior art because Evans et al teach that protozoa oocysts including *Eimeria maxima, E. mitis, E. tenella, E. acevulina, E. brumetti, E. necatrix, E. praecox* and mixtures thereof including multiple strains can be give in a

single vaccine. Vaccines are known as pharmaceutical compositions that are used to immunize subjects and are thereby given in immunizing doses and can include determination by storage half-life determinations. The compositions of Evans et al disclose that the same concentration of oocysts are used to prepare their composition as those disclosed in the claimed invention. Therefore, this claim limitation is met by the prior art.

IV. Response to Argument Traversing the Rejection of claims 1, 4-30, 113-116, 118-119, 136-143, 146, 148, 149-150 and 153-154 under 35 U.S.C. 103(a) as unpatentable over Evans et al in view of Brown et al.

Appellant urges that Brown et al is relied upon by the Examiner for its disclosure of *P. acnes*. Appellant urges that Brown that all of the claims are patentable over Evans et al. and over any combination of Evans. et al and Brown et al. Appellant urges that the product-by-process limitations of claim impose structural limitations and distinguishes the claimed invention from the cited references. Appellant urges that there is no disclosure in Evans et al. nor Brown et al. that teach a composition substantially free of bacterial contaminants removed by tangential flow filtration and there is no motivation to combine the prior references. Appellant urges that neither of the cited references suggest separating nonviable bacterial or other contaminants that may be present in the composition or during processing. Appellant urges that Evans et al. fail to teach or disclose a filter size small enough to prevent sporulated oocysts from entering the pores but large enough to allow bacteria to pass through the pores.

Appellant urges that the filter used in tangential flow is larger enough to allow bacteria to pass.

Appellant urges that repeated washings as taught by Evans et al do not remove the potassium dichromate form the oocysts suspension. Applicant urges that Evans et al do not disclose the use of tangential flow filtration much less the use of filter pore sizes small enough to prevent sporulated oocysts form entering the pores but large enough to allow bacteria to pass through. Applicant urges that there is no teaching or suggestion of the desirability of separating the oocysts form non-viable bacterial or other contaminants that may be present in the oocysts suspension.

Appellant urges that Claim 1 and Evans et al have been discussed above. Appellant urges that Brown is directed to methods for improving immunization against coccidiosis and other bacterial, viral or parasitic diseases in poultry. Appellant urges that Brown et al fail to disclose or suggest a composition that is substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow...".

It is the Examiner's position that the combination of references teach the claimed invention.

To address Applicant's comments regarding, Evans et al combined with Brown et al, it is the Examiner's position that the claimed compositions and the compositions as set forth in the combination of prior art teachings are not structurally different. The claims are directed to composition comprising viable sporulated oocysts (a product). The claims require that the composition comprises: 1) "sporulated oocysts", 2) wherein the oocysts are at least about 10,000 oocysts per milliliter and 3) wherein the composition is sterile and contains less than about 0.4% of alkali metal dichromate. Claim limitations such as "said composition being substantially free of bacterial contaminants which are present in said source but have been separated from said oocysts by tangential flow filtration of an aqueous process medium containing said oocysts and said oocysts" and "bacterial contamination using a filter membrane having a pore size such that sporulated oocysts cannot enter the pores but said bacterial contaminants can pass through the pores" are process limitations. The combination of prior art teachings (Evans et al and Brown et al) teach the claimed invention because Evans et al teach compositions comprising: 1) sporulated oocysts, 2) the oocysts are at least about 10,000 oocysts per milliliter and 3) the composition is sterile and contains less than about 0.4% of alkali metal dichromate and Brown et al teach that *Propionibacterium acnes* can be used for stimulating non-specific cell mediated immune responses in poultry at an age as early as day one or even *in ovo* and to

combat coccidiosis and other poultry diseases. Thus, one of ordinary skill in the art would be motivated to combine the teachings of Evans et al. and Brown et al. to arrive at the claimed invention.

In response to applicant's argument that there is no motivation to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the instant case, one of ordinary skill in the art would have a reasonable expectation of success in using the compositions of Brown et al and Evans et al as combined because Brown et al teach that *P. acnes* can be used to combat coccidiosis at an age as early as day one or even *in ovo* and other poultry diseases and Conkle et al teach that the sporulated oocysts of the invention can be formulated into a vaccine against avian coccidiosis.

To address Appellant's comments regarding process limitations such as removal of bacterial contaminants, the use of tangential flow filtration and the used of filter membranes with specific pore sizes (which includes the limitations in claims 153-154), it should be remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964

(CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

It should be noted that the Examiner disagrees with Applicant's assertion that "the prior art does not disclose separating the oocysts from bacterial or other contaminants that may be present in the sporulation medium or in the bleached oocysts suspension". Evans et al teach the removal of contaminants from the suspension comprising the oocysts. See page 7.

Therefore, combination of references teach the claimed invention.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Vanessa L. Ford

Conferees:

Brenda Brumback

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Long Le

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600